

CHAPTER 2. MEDICAL MATERIEL INSTRUCTIONS

2-1. SUBMITTING MEDICAL/DENTAL PRODUCT QUALITY DEFICIENCY REPORTS (M/DPQDR) – [FORMERLY MEDICAL MATERIEL COMPLAINTS (SF 380S)]

a. All medical materiel complaints, regardless of procurement source, should be submitted on a Medical or Dental Product Quality Deficiency Report (M/DPQDR). A M/DPQDR should be submitted to report materiel or equipment that has been determined to be harmful and/or defective that may result in death, injury, or illness. The M/DPQDRs are categorized into two types:

- Category I: Materiel that has been determined by use or testing to be harmful or defective to the extent that its use has or may cause death, injury, or serious illness.
- Category II: Drugs, devices, supplies, or equipment that is suspected of being harmful, defective, deteriorated, or unsatisfactory because of malfunction or design, which are attributable to faulty materiel, workmanship and/or quality inspection, or performance or are otherwise unsuitable for use.

b. An M/DPQDR is the customer's way of alerting the system that there is a quality deficiency with a medical or dental product. Deficiencies should be submitted on standard and nonstandard items. It is also the vehicle for submitting Safe Medical Device (SMD) incidents. Examples of discrepancies which should be reported on the M/DPQDR are:

- Wrong or deficient labeling
- Foreign or particulate matter in liquids and solids
- Imperfectly manufactured items which are off-color, off-taste, and off-odor
- Suspected sub-potency or super-potency
- Defective devices
- Pinholes in tubing
- Faulty calibrations
- Systemic equipment failures
- Poor quality products

c. The submitter will receive a copy of the e-mail that has been sent to DSCP, the Defense Medical Standardization Board (DMSB) and the Services' Medical Logistic Offices at Ft Detrick. Once the form is received, DSCP will assign a Report Control Number (RCN) in the Product Data Reporting and Evaluation Program (PDREP), and respond back to you normally within two days. For more information about the PDREP program go to the following website:

<http://www.nslcptsmh.navsea.navy.mil/pdrep/pdrep.htm>

d. Report the circumstances of Category I (Type I complaints) immediately to DSCP, through the M/DPQDR, or by telephone.

(1) During normal duty hours (0700 - 1700 hours Eastern Time), call the DSCP Emergency Supply Operations Center (ESOC) at DSN 444-2111/2112, or commercial 215 737-2112. A telefax may also be sent to: Commercial 215 737-2081/7109 or DSN 444-2081/7109.

(2) After duty hours, the numbers called above will automatically transfer to the Staff Duty Officer. If the transfer does not occur or the call is not answered, call the following numbers: DSN 444-2341 or commercial 215 737-2341.

e. The *21 CFR* prescribes reporting certain materiel/equipment conditions to the FDA under the Safe Medical Devices Act (SMDA). Logistics personnel will coordinate and provide a copy of the Complaint Form to the Risk Manager as part of the Risk Management Program. The Risk Manager is required under Joint Commission on Accreditation of Healthcare Organization (JCAHO) to review the SMDA information on the Complaint Form and assess the potential risk.

A sample of the M/DPQDR is shown at Appendix A.

2-2. DEPARTMENT OF DEFENSE MEDICAL MATERIEL QUALITY CONTROL (DOD-MMQC) MESSAGES AND DEPARTMENT OF THE ARMY MEDICAL MATERIEL INFORMATION (MMI) MESSAGES

a. The DoD-MMQC messages is a Tri-Service centralized reporting system developed to maintain a readiness posture by providing our MTOE activities, ships, and other deployed field units the same quality assurance (QA) information afforded fixed/TDA facilities. The DoD-MMQC process is an Integrated Medical Logistics Group initiative, designed to simultaneously disseminate QC information and rapidly notify hospitals, clinics, and medical units aboard ships or on foreign soil of potentially hazardous medical materiel. These messages contain urgent QA data emanating from pharmaceutical and/or medical device and equipment manufacturers regarding their products.

b. Once received at the Defense Supply Center Philadelphia (DSCP), research is conducted by DSCP and USAMMA's Distribution Operations Center (DOC) (MCMR-MMO-SO) to equate the product with National Stock Numbers (NSNs). The USAMMA's DOC then incorporates information into the DoD-MMQC message format that contains all Service-specific requirements, Point of Contact (POC), reason for message, disposition instructions, and any other product related information. The program's primary purpose is to aid the Service-specific logisticians, supply managers, pharmacists, clinicians, medical maintenance personnel, in assuring that the proper use, handling, and return of recalled product is accomplished to protect patient safety.

c. The recalls are classified as follows:

(1) Class I: A situation in which there is a reasonable probability that use of, or exposure to, a dangerous product will cause serious adverse health consequences or death.

(2) Class II: A situation in which the use of, or exposure to, a dangerous product may cause adverse health consequences.

(3) Class III: A situation in which the use of, or exposure to, a dangerous product is not likely to cause adverse health consequences.

d. The DOC also disseminates Army Medical Materiel Information (MMI) messages that contain information specific to the Army only.

e. These messages are available via two media (Reference Department of the Army SB dated 20 January 2007, *SB 8-75-S1*, paragraph 4-6 and SB dated 30 November 2006, *SB 8-75-11*, paragraph 4-2):

(1) The World Wide Web (WWW) (available on the USAMMA Homepage at <http://www.usamma.army.mil>. Select "DoD-MMQC Messages" and follow appropriate prompts.

(2) Electronic Mail. Register to receive DoD-MMQC and MMI messages via e-mail by subscribing on USAMMA's website (address above). Select "DoD-MMQC Messages" the "Subscribe to MMQC Messages Here" and provide all required information.

f. These messages are also disseminated via:

(1) File-transfer protocol (FTP) to USAMMCE (Germany) and 16th MLB (Korea)

(2) Joint Medical Asset Repository (JMAR)

(3) Defense Medical Logistics Supply System (DMLSS)

2-3. SAFE MEDICAL DEVICE ACT (SMDA) OF 1990

a. References:

(1) *AR 40-61*, Chapter 4, Section V, Para 4-13 and 4-14

(2) *FDA Medical Device Report (MDR) Regulation* (Website: www.fda.gov)

(3) *Medical/Dental Product Quality Deficiency Report (M/DPQDR)*

b. Effective 28 November 1991, all Medical Treatment Facilities (MTFs) are required to report device-related deaths, serious injuries and reportable malfunctions.

c. The M/DPQDR and the MedWatch 3500A Mandatory Reporting Form, will continue to be used in submitting the incidents, and is not limited to devices, and includes equipment as well as pharmaceuticals. All Activities should continue to submit M/DPQDRs, IAW *AR 40-61*, dated 28 Jan 2006, Chapter 4, Section V, Para 4-13 and 4-14.

d. M/DPQDR reports are not defined as Type I, Type II or Type III complaints [as previously identified with Medical Materiel Complaints (SF 380's)]. Categories of the M/DPQDR are as a Category 1 or 2:

- A category 1 complaint is an item or event that could cause serious injury or illness or loss of life. Category 1 can only be submitted with the approval of a medical officer.

- All others are Category 2.

e. User-facilities such as hospitals and nursing homes are legally required to report suspected medical device-related deaths to both the Food and Drug Administration (FDA) and the manufacturer, if known, and serious injuries to the manufacturer or to FDA, if the manufacturer is unknown. These reports must be made on the MedWatch 3500A Mandatory Reporting Form.

f. The statutory authority for the MDR regulation is section 519(a) of the Federal Food Drug & Cosmetic (FFD&C) Act as amended by the SMDA of 1990. The SMDA requires user facilities to report:

- (1) device-related deaths to the FDA and the device manufacturer;
- (2) device-related serious injuries to the manufacturer, or to FDA if the manufacturer is not known; and
- (3) submit to FDA on an annual basis a summary of all reports submitted during that period

g. The SMDA requires FDA to issue regulations requiring distributors to report device-related deaths, serious injuries and reportable malfunctions. In addition, the SMDA requires distributors and manufacturers to certify to FDA the number of MDR reports filed or that no reports have been filed. All manufacturers of finished medical devices and components which are ready for use, including foreign manufacturer's are now subject to the requirements of the MDR regulation, despite registration status.

2-4. SUBMITTING SUPPLY DISCREPANCY REPORTS (WebSDR) – [FORMERLY REPORTS OF DISCREPANCY (SF 364)]

a. All Supply Discrepancy Reports should be done electronically under the Department of Defense's Supply Discrepancy Reporting (SDR) system created by the Defense Logistics Agency (DLA). The Defense Automatic Addressing Service Center (DAASC) is responsible for the development and support of this project.

b. The goal of WebSDR is to move SDRs into an integrated transactional environment thereby providing an effective means to report and measure discrepancy related data and pipeline performance and to help achieve near real time SDR reporting, enable Perfect Order Fulfillment computations, facilitate interoperability internal and external to DoD, and maximize the economy, efficiency, effectiveness of the reporting process.

c. To submit a SDR on-line, go to: <https://www.daas.dla.mil/websdr>

d. You must register, providing all information required; once complete, submit and you will be provided a password. Once received, then comply with instructions outlined. For more information on this web site and the WebSDR Application, choose "Contact Us" (top right hand corner) on web page.

2-5. POINT OF CONTACT

Questions regarding these medical materiel instructions may be directed to:

USAMMA
ATTN: MCMR-MMO-SO
1423 Sultan DR
Fort Detrick MD 21702-5001
DSN 343-4300/3242 or Commercial 301-619-4300/3242